GANPATUNIVERSITY

CENTRE FOR HEALTH & APPLIED SCIENCES

Teaching Scheme, Examination Scheme

&

Syllabus

M.Sc. Chemistry (Pharmaceutical Analysis)

Semester I & II

(Effective from July 2019)

GANPAT UNIVERSITY

CENTRE FOR HEALTH AND APPLIED SCIENCES

TEACHING AND EXAMINATION SCHEME

Program	M. Sc. Chemistry	Branch	Pharm. Analysis	Semester	I	Version	3.0.0.0
Effective from	2019-20	Effective for batches admitted onwards	July 2019				

S.N	Subject Code	Subject Name	Theory / Practical	Teaching Scheme		Examination Scheme			
				Hours Per Week	Credit	Marks			Total Marks
						CE	SE	ES	
1	MPHA1MAT	Modern Pharmaceutical Analytical Techniques	Theory	4	4	20	20	60	100
2	MPHA1QCA	Quality Control and Quality Assurance	Theory	4	4	20	20	60	100
3	MPHA1SBA	Stability Testing and Biochemical Analysis	Theory	4	4	20	20	60	100
4	MPHA1SEM	Seminar/Assignment	Theory	6	6	20	20	60	100
5	MPHA1PRA	Practical - I	Practical	12	6	40	40	120	200
		Total		**30**	**24**	**120**	**120**	**360**	**600**

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CENTRE FOR HEALTH AND APPLIED SCIENCES

TEACHING AND EXAMINATION SCHEME

Program	M. Sc. Chemistry	Branch	Pharm. Analysis	Semester	II	Version	3.0.0.0
Effective from	2019-20	Effective for batches admitted onwards	July 2019				

S.N	Subject Code	Subject Name	Theory / Practical	Teaching Scheme		Examination Scheme			
				Hours Per Week	Credit	Marks			Total Marks
						CE	SE	ES	
1	MPHA2HSM	Hazards and Safety Management	Theory	4	4	20	20	60	100
2	MPHA2PHV	Pharmaceutical Validation	Theory	4	4	20	20	60	100
3	MPHA2PMA	Pharmacopoeial Methods of Analysis	Theory	4	4	20	20	60	100
4	MPHA2SEM	Seminar	Theory	6	6	20	20	60	100
5	MPHA2PRA	Practical - II	Practical	12	6	40	40	120	200
		Total		**30**	**24**	**120**	**120**	**360**	**600**

GANPAT UNIVERSITY

CENTRE FOR HEALTH AND APPLIED SCIENCES

Program	M. Sc. Chemistry	Branch/Spec.	Pharmaceutical Analysis
Semester	I	Version	3.0.0.0
Effective from Academic Year	2019-20	Effective for the batches Admitted onwards	July 2019
Subject code	MPHA1MAT	Subject Name	Modern Pharmaceutical Analytical Techniques

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, Fluorimeter, NMR, Mass spectrometer, IR, HPLC, GC etc.

Learning Outcome:

- Knowledge of molecular and atomic spectroscopic methods of analysis
- Understand various separation techniques for the analysis of drugs and biomolecules
- Application of instrumental techniques for qualitative and quantitative analysis of organic substances
- Analyse and select best suitable analytical techniques for the estimation of drugs and pharmaceuticals
- Evaluation of analytical methods used for thermal analysis
- Create analytical skills for identification and quantification of drugs using modern analytical techniques

Syllabus- Theory

Unit	Content	Hrs
1	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV/Visible Spectroscopy **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy	15
2	**Spetrofluorimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications	15
3	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy **Mass Spectroscopy**: Principle, Theory, Instrumentation, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	15
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing	15

References

1	Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.
2	Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3	Instrumental methods of analysis – Willards, 7th edition, CBSpublishers.
4	Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi,1997.
5	Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.
6	Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi,1997.
7	Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

GANPAT UNIVERSITY												
CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	I				Version	3.0.0.0						
Effective from Academic Year				2019-20	Effective for the batches Admitted onwards					July 2019		
Subject code	MPHA1QCA			Subject Name	Quality Control and Quality Assurance							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Learning Outcome:

	knowledge about analysis of raw materials, finished pharmaceuticals, packaging materials, and perform In process quality control and finished products quality control testing as per IP, BP.
	Understand and outline about QC, QA concepts as well as GMP, GLP, CPCSEA, ICH-QSEM guidelines.
	Applicability of GMP guidelines as per WHO, US-FDA, EMEA to quality testing, management, manufacturing, and the control of pharmaceutical products.
	Analyse and interpret certain GMP aspects like training, hygiene, records, maintenance, sanitation, utilities and maintenance of sterile areas, control of contamination etc.
	Evaluate all documentation like SOPs, reports, forms and formats in pharmaceutical industry.
	Create a skill for good manufacturing practices, good laboratory practices and QC QA principles in pharmaceutical industries and R & D centre.

Syllabus- Theory

Unit	Content	Hrs
1	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12
3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	12

5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12

References

1	Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2	Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3	Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I& II, 2nd edition, WHO Publications, 1999.
4	How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5	The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6	Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7	ICH guidelines
8	ISO 9000 and total quality management
9	The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10	QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11	Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12	Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13	Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14	Schedule M and Schedule N.
15	Packaging of Pharmaceuticals.

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CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	I				Version	3.0.0.0						
Effective from Academic Year				2019-20	Effective for the batches Admitted onwards					2019-20		
Subject code	MPHA1SBA			Subject Name	Stability Testing and Biochemical Analysis							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites	
Nil	
Scope and Objectives:	
	This course deals with the various aspects of stability testing of drug substance and products, ICH guidelines, bioanalysis, stability indicating assays, Bioanalytical method development and validation, Photostability. It covers the important aspects like force degradation, various ICH guidelines, extraction procedures etc.
Learning Outcome:	
	Knowledge of the concept of stability testing and new drug development
	Understand methodology of stress testing according to regulatory requirements and stability indicating assay methods
	Applicability of biochemical analysis of drugs and metabolites
	Analyse parameters for photostability testing of new active substances and medicinal products
	Evaluate methodology for analytical and bioanalytical method development and validation according to regulatory requirements
	Create skill for developing best suitable analytical methods for analysis of drugs in formulations as well as in biological fluids with stability data

Syllabus- Theory

Unit	Content	Hrs
1	Stability Testing: Definitions, ICH guidelines for stability testing, Factors affecting stability of a formulation, Stabilizers and Methods of stabilization. Drug development cycle and stability-testing: Role and types of stability studies during different stages of drug and product development	12
2	Stress testing of drug substances: Role, regulatory aspects, protocols / approaches, practical considerations. Stability-indicating assays: Definition, regulatory requirement, steps in development, practical considerations.	12
3	Photo stability testing: Photostability testing of new active substances and medicinal products, light sources and options, types of chambers, presentation of samples, practical considerations, confirmatory testing. Stability testing of biotechnological products: Typical stability testing issues of biotechnological vis-à-vis conventional products, considerations in ICH Q5C guidelines.	12
4	Analysis of drugs/metabolites in biological fluids like urine, blood and tissues. Biochemical analysis of drugs, estimation of endogenous materials (CH, Proteins/amino acids/Lipids/Vitamins etc.) and enzymatic analysis	12
5	Bioanalytical method development: Extraction procedures, techniques of analysis, methodology, HPLC method development overview, validation parameters for Bioanalytical methods	12

References

1	ICH Guideline for Impurity Determination and Stability Studies..
2	Identification and Determination of Impurities in Drugs, S. Gorog, Elsevier.
3	Analysis of Drug Impurities, R. J. Smith and M. L. Webb.
4	ICH Photostability guidelines
5	ICH guidelines for biotechnology derived products
6	Micheal E. Swartz, Analytical method development and validation

7	D.C.Garratt, The quantitative analysis of drugs, second edition
8	Method of protein analysis by Istran Kerese
9	Jems T Carstenson. Drug stability- Principles and Practices. 2nd edition, Marcel Deccer.
10	Venn RF, Principle and Practice of Bioanalysis, Francis & Taylor
11	ICH guidelines for Bioanalytical method development and validation

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CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	I				Version	3.0.0.0						
Effective from Academic Year	2019-20				Effective for the batches Admitted onwards	July 2019						
Subject code	MPHA1SEM			Subject Name	Seminar							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	6	-	-	6	Theory	20	20	60	100	Theory	-	-
Credit	6	-	-	6	Practical	-	-	-	-	Practical	-	-
Pre-requisites												
Nil												
Scope and Objectives:												
	This course designed to strengthen the literature collection, computer writing and editing, referencing and presentation skill of the students by regular submission of assignments and class seminars. This course contains the selection of appropriate topics from the field of pharmaceutical sciences, collecting and compiling the data, preparation of content, presentations, submission, tests, viva voce etc.											
Learning Outcome:												
	Knowledge of the latest development in the area of pharmaceutical sciences											
	Understand the use of the library and internet resources for the referencing and literature purpose											
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way											
	Analyse the problems and strengthen ability for presentations and defending the viva voce											
	Evaluate the hypothesis, study design, method and results in a systemic manner											
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion											

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CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	I				Version	3.0.0.0						
Effective from Academic Year	2019-20				Effective for the batches Admitted onwards	July 2019						
Subject code	MPHA1PRA				Subject Name	Practical - I						
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	-	-	12	12	Theory	-	-	-	-	Theory	-	-
Credit	-	-	6	6	Practical	40	40	120	200	Practical	6 hr.	6 hr.

Learning Outcome

Knowledge of how to perform validation of analytical methods for drugs

Understand estimation of various drugs from formulations using spectroscopic techniques

Applications of chromatographic techniques in identification and quantification of drugs

Analyse different official or unofficial drugs by multicomponent applications of UV Visible spectroscopy

Evaluate and select best analytical techniques for quantification of drugs by performing suitable experiments

Create skills in handling various analytical instruments as well as their operations according to standard operating procedures

Content of Practicals

1. Practicals based on stability studies
2. Experiments based on assay of drugs and their formulations by UV Vis spectrophotometer
3. Practicals based on simultaneous estimation of multi component containing formulations by UV spectrophotometry
4. Experiments based on other applications of UV spectrophotometry like pka determination,
5. Experiments based on different chromatographic techniques
6. Experiment based on estimation of riboflavin/quinine sulphate by fluorimetry and quenching effect study by fluorimetry
7. Estimation of sodium/potassium by flame photometry
8. Estimation of selected endogenous materials in biological fluids
9. Experiments based on force degradation study
10. Practicals based on separation of amino acids by chromatographic technique

References

1. Pharmacopoeia (IP, BP, USP)
2. Merck Index
3. Martindale: The Extra Pharmacopoeia
4. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
5. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delh.
7. A.I. Vogel, Textbook of Quantitative Chemical Analysis, 5th ed., Addison Wesley Longman Singapore
8. G. W. Eving, Instrumental Methods of Chemical Analysis, 5th ed.,McGraw Hill Book Company

9. Willard, Merritt, Dean, and Settle, Instrumental Methods of Analysis, 7th ed., CBS Publishers & Distributors
10. Allen J. Bard and Larry R. Faulkner, Electro-chemical Methods,2nd ed., John Wiley & Sons
11. G.D. Christian, Analytical Chemistry, 6th ed, John Wiley & Sons
12. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	II				Version	3.0.0.0						
Effective from Academic Year	2019-20				Effective for the batches Admitted onwards	July 2019						
Subject code	MPHA2HSM			Subject Name	Hazards and Safety Management							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provide the principle based approach to solve the complex tribulations.

Learning Outcome:

	Knowledge of the various energy resources and ecosystems
	Understand air and chemical based hazards and its regulation
	Application of fire protection systems in pharmaceutical industry
	Analyze and identify different hazards in work place and selecte best practice for its prevention and control
	Evaluation of critical hazard and risk management systems in industry
	Create skills to identify, minimize or eliminate different work place hazards

Syllabus- Theory

Unit	Content	Hrs
1	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b)Water resources; c) Mineral resources; d) Energy resources e)Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes	12
2	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system	12
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept	12
4	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety &hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems-relief valves, flares, scrubbers	12
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment &Risk management methods &Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme & safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services	12

References

1	Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2	"Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3	BharuchaErach, The Biodiversity of India, Map in Publishing Pvt. Ltd., Ahmedabad
4	Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

GANPAT UNIVERSITY												
CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	II				Version	3.0.0.0						
Effective from Academic Year			2019-20		Effective for the batches Admitted onwards					July 2019		
Subject code	MPHA2PHV		Subject Name		Pharmaceutical Validation							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Learning Outcome:

- Knowledge about the various concepts of calibration, qualification, validation and intellectual property rights.
- Understand the importance of validation and how it can be applied to industry to improve the quality of product
- Application of knowledge in qualification of various equipments and instruments as well as process validation of different dosage forms
- Analysis of pharmaceutical substance, drugs, instruments and computer system
- Evaluate the data obtained from the validation, calibration and qualification
- Create skill to perform the validation of analytical method for estimation of drugs and cleaning validation of equipments employed in the manufacture of pharmaceuticals

Syllabus- Theory

Unit	Content	Hrs
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management).	10
2	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS	10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	10
4	Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals andaerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP	10
5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place(CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature- 21CFR Part11and GAMP	10
6	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent	10

	applications- provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices	

References

1	B. T.Loftus & R. A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,N.Y.
2	The Theory &Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3	Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4	Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton & Agalloco
5	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press
8	Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton(Ed.)and James Agalloco(Ed.),Marcel Dekker
9	Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam,Y.C.Lee,Yue .Zhang, WileyInterscience
10	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11	Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press
12	LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

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CENTRE FOR HEALTH AND APPLIED SCIENCES

Program	M. Sc. Chemistry	Branch/Spec.	Pharmaceutical Analysis
Semester	II	Version	3.0.0.0
Effective from Academic Year	2019-20	Effective for the batches Admitted onwards	July 2019
Subject code	MPHA2PMA	Subject Name	Pharmacopoeial Methods of Analysis

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	4	-	-	4	Theory	20	20	60	100	Theory	1 hr.	3 hr.
Credit	4	-	-	4	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This course is designed to learn the pharmacopoeia, monographs, limit tests, various physical tests, biological and microbiological tests, dissolution tests, weight and content uniformity tests, impurities and its sources etc. This syllabus covers various pharmacopoeial methods of analysis for drugs and excipients like electroanalytical, spectroscopic and chromatographic methods.

Learning Outcome:

- Knowledge of pharmacopoeia, drug monographs, limit tests, sources of impurities, weight/content uniformity tests, biological test etc.
- Understand the dissolution tests and its importance in analysis.
- Applications of various pharmacopoeial tests for analysis of inorganic residue, solvents and biological matrix
- Analysis of drugs and excipients using various pharmacopoeial methods of analysis like electroanalytical, spectroscopic and chromatographic methods
- Evaluate and select suitable spectroscopic or chromatographic methods for qualitative and quantitative analysis of drugs
- Create skills to identify and quantify various drugs and formulations using pharmacopoeial methods of analysis

Syllabus- Theory

Unit	Content	Hrs
1	Pharmacopoeia: Introduction, overview of IP, monographs Physical tests: Viscosity, melting point, boiling point / range, water content, osmolality /osmolarity, refractive index, loss on drying, loss on ignition, optical rotation, pH and specific gravity. Limit tests: Tests for arsenic, lead, chloride, sulfate and heavy metals.	12
2	Special tests: Inorganic impurities, residual solvents, etc. Microbiological assays: Anti-microbial effectiveness testing, microbial limit tests, sterility test. Biological tests: Antibiotics, microbial assays, bacterial endotoxins test.	12
3	Dissolution tests: Types of dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms; coated, uncoated and enteric-coated tablets, gelatin capsules, etc. Miscellaneous tests: Tests for vitamins, Sources of impurities in pharmaceutical products Introduction to weight uniformity, content of active ingredients and content uniformity	12
4	Pharmacopoeial methods for analysis of drugs/formulation: Electroanalytical methods like pH metry, potentiometry, conductometry, polarimetry, polarography etc. Chromatographic methods for identification and quantification of drugs like TLC, HPLC, GC	12
5	Spectroscopic methods for qualitative and quantitative analysis of drugs like UV/Vis. Spectrophotometry, colorimetry, IR, fluorimetry etc. Applications of pharmacopoeial methods for analysis of common excipients/additives in bulk and formulations	12

References

1. Indian Pharmacopoeia, Vol. I and II ,The Controller of Publications, Govt. of India, New Delhi
2. The International Pharmacopoeia, Vol. 1,2,3,4, Third Edition, General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage Forms

3	Pharmaceutical Analysis – Modern Methods, Part A and B ,JamesW. Munson
4	Principle of Inorganic Chemistry by Block and Soine
5	Text book of Inorganic Chemistry by Kasture
6	Principle of Instrumental Analysis by Vidyasagar
7	Instrumental Analysis by Ashutosh Kar
8	Pharmacopoeia: USP, BP, EP, JP
9	A.I. Vogel, Textbook of Quantitative Chemical Analysis, 5th ed., Addison Wesley Longman Singapore
10	G. W. Eving, Instrumental Methods of Chemical Analysis, 5th ed.,McGraw Hill Book Company
11	Willard, Merritt, Dean, and Settle, Instrumental Methods of Analysis, 7th ed., CBS Publishers & Distributors
12	Allen J. Bard and Larry R. Faulkner, Electro-chemical Methods,2nd ed., John Wiley & Sons
13	G.D. Christian, Analytical Chemistry, 6th ed, John Wiley & Sons
14	Instrumental Analysis by Chatwal and Anand

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CENTRE FOR HEALTH AND APPLIED SCIENCES												
Program	M. Sc. Chemistry				Branch/Spec.	Pharmaceutical Analysis						
Semester	II				Version	3.0.0.0						
Effective from Academic Year	2019-20				Effective for the batches Admitted onwards	July 2019						
Subject code	MPHA2SEM			Subject Name	Seminar							
Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	6	-	-	6	Theory	20	20	60	100	Theory	-	-
Credit	6	-	-	6	Practical	-	-	-	-	Practical	-	-

Pre-requisites

Nil

Scope and Objectives:

This course designed to strengthen the literature collection, computer writing and editing, referencing and presentation skill of the students by regular submission of assignments and class seminars. This course contains the selection of appropriate topics from the field of pharmaceutical sciences, collecting and compiling the data, preparation of content, presentations, submission, tests, viva voce etc.

Learning Outcome:

	Knowledge of the latest development in the area of pharmaceutical sciences
	Understand the use of the library and internet resources for the referencing and literature purpose
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way
	Analyse the problems and strengthen ability for presentations and defending the viva voce
	Evaluate the hypothesis, study design, method and results in a systemic manner
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion

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Subject code	MPHA2PRA	Subject Name	Practical - II

Teaching scheme					Examination scheme							
	Le	Tu	Pr	Total	Marks	CE	SE	ES	Total	Duration	SE	ES
Hours	-	-	12	12	Theory	-	-	-	-	Theory	-	-
Credit	-	-	6	6	Practical	40	40	120	200	Practical	6 hr.	6 hr.

Learning Outcome

Knowledge of how to develop and validate analytical methods for drugs

Understand importance of dissolution techniques in drug analysis

Applications of chromatographic techniques in identification and quantification of drugs

Analyse and select different official or unofficial drugs by multicomponent applications of UV Visible spectroscopy

Evaluate and select best electro analytical techniques for quantification of drugs

Create skills in handling various analytical instruments as well as their operations according to standard operating procedures

Content of Practicals

1. Practicals based on pharmacopoeial limit tests for chloride, sulphate, iron, arsenic, heavy metals
2. Practical based on weight uniformity and content uniformity
3. Experiments based on dissolution studies
4. Practicals based on analytical method validation parameters viz. linearity, precision, accuracy, LOD, LOQ
5. Practicals based on selected pharmacopoeial monographs
6. Experiments based on separation of sugars or amino acids by chromatographic methods like TLC, paper chromatography
7. Experiments based on electroanalytical techniques like pH metry, potentiometry, conductometry, polarimetry etc.
8. Practicals based on analysis of selected excipients by pharmacopoeial methods
9. Experiments based on analysis of drugs by UV Vis spectrophotometer
10. Practicals based on multicomponent analysis applications of UV Visible spectrophotometry
11. Identification tests of drugs/formulation by different spectroscopic and chromatographic techniques
12. Calibration and validation of analytical instruments

References

1. Pharmacopoeia (IP, BP, USP)
2. Merck Index
3. Martindale: The Extra Pharmacopoeia
4. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
5. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. A.I. Vogel, Textbook of Quantitative Chemical Analysis, 5th ed., Addison Wesley Longman Singapore
9. G. W. Eving, Instrumental Methods of Chemical Analysis, 5th ed.,McGraw Hill Book Company
10. Willard, Merritt, Dean, and Settle, Instrumental Methods of Analysis, 7th ed., CBS Publishers & Distributors
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